Current Status of the Claims:

This listing of claims will replace the listing of claims in the application:

Listing of Claims:

1. (Original) A stable pharmaceutical formulation comprising a dopamine receptor agonist and one or more delivery-enhancing agent(s), wherein said formulation following mucosal administration to a mammalian subject yields a peak concentration of said dopamine receptor agonist in a central nervous system tissue or fluid of said subject that is 5% or greater compared to a peak concentration of said dopamine receptor agonist in a blood plasma of said subject.

2. (Original) The formulation of claim 1, wherein said mucosal administration involves delivery of said formulation to a nasal mucosal surface of said subject.

3. (Original) The formulation of claim 1, wherein the dopamine receptor agonist is apomorphine or a pharmaceutically acceptable salt or derivative thereof.

4. (Original) The formulation of claim 1, wherein said dopamine receptor agonist is administered to said subject in an effective dose of between about 0.25 and 2.0 mg.

5. (Original) The formulation of claim 1, wherein said delivery-enhancing agent(s) is/are selected from:

(a) an aggregation inhibitory agent;

(b) a charge modifying agent;

(c) a pH control agent;

(d) a degradative enzyme inhibitory agent;

(e) a mucolytic or mucus clearing agent;

(f) a ciliostatic agent;

(g) a membrane penetration-enhancing agent selected from (i) a surfactant, (ii) a bile salt, (ii) a phospholipid additive, mixed micelle, liposome, or carrier, (iii) an alcohol, (iv) an enamine, (v) an NO donor compound, (vi) a long-chain amphipathic molecule (vii) a small hydrophobic penetration enhancer; (viii) sodium or a salicylic acid derivative; (ix) a glycerol ester of acetoacetic acid (x) a clyclodextrin or beta-cyclodextrin derivative, (xi) a medium-chain fatty acid, (xii) a chelating agent, (xiii) an amino acid or salt thereof, (xiv) an N-acetylamino acid or salt thereof, (xv) an enzyme degradative to a selected membrane component, (ix) an inhibitor of fatty acid synthesis, or (x) an inhibitor of cholesterol synthesis; or (xi) any combination of the membrane penetration enhancing agents recited in (i)-(x);

(h) a modulatory agent of epithelial junction physiology;

(i) a vasodilator agent;

(j) a selective transport-enhancing agent; and

(k) a stabilizing delivery vehicle, carrier, support or complex-forming species with which the dopamine receptor agonist is effectively combined, associated, contained, encapsulated or bound resulting in stabilization of the dopamine receptor agonist for enhanced mucosal delivery, wherein the formulation of said dopamine receptor agonist with said one or more delivery-enhancing agents provides for increased bioavailability of the dopamine receptor agonist in a central nervous system tissue or fluid of said subject.

6. (Original) The formulation of claim 1, wherein said delivery-enhancing agent(s) is/are selected from the group consisting of citric acid, sodium citrate, propylene glycol, glycerin, L-ascorbic acid, sodium metabisulfite, edetate disodium, benzalkonium chloride, sodium hydroxide and mixtures thereof.

7. (Original) The formulation of claim 1, wherein said formulation mucosally administered to said subject yields a peak dopamine receptor agonist

concentration in a cerebral spinal fluid of said subject that is between about 5-10% of the peak dopamine receptor agonist concentration in the blood plasma of said subject.

8. (Original) The formulation of claim 1, wherein said formulation mucosally administered to said subject yields a peak dopamine receptor agonist concentration in a cerebral spinal fluid of said subject that is about 10% or greater compared to the peak dopamine receptor agonist concentration in the blood plasma of said subject.

9. (Original) The formulation of claim 1, wherein said formulation mucosally administered to said subject yields a peak dopamine receptor agonist concentration in a cerebral spinal fluid of said subject that is about 15% or greater compared to the peak dopamine receptor agonist concentration in the blood plasma of said subject.

10. (Original) The formulation of claim 1, wherein said formulation mucosally administered to said subject yields a peak dopamine receptor agonist concentration in a cerebral spinal fluid of said subject that is about 20% or greater compared to the peak dopamine receptor agonist concentration in the blood plasma of said subject.

11. (Original) The formulation of claim 1, wherein said formulation mucosally administered to said subject yields a peak dopamine receptor agonist concentration in a cerebral spinal fluid of said subject that is about 25% or greater compared to the peak dopamine receptor agonist concentration in the blood plasma of said subject

12. (Original) The formulation of claim 1, wherein said formulation mucosally administered to said subject yields a peak dopamine receptor agonist concentration in a cerebral spinal fluid of said subject that is about 30% or greater compared to the peak dopamine receptor agonist concentration in the blood plasma of said subject.

13. (Original) The formulation of claim 1, wherein said formulation mucosally administered to said subject yields a peak dopamine receptor agonist concentration in a cerebral spinal fluid of said subject that is about 35% or greater compared to the peak dopamine receptor agonist concentration in the blood plasma of said subject.

14. (Original) The formulation of claim 1, wherein said formulation mucosally administered to said subject yields a peak dopamine receptor agonist concentration in a cerebral spinal fluid of said subject that is about 40% or greater compared to the peak dopamine receptor agonist concentration in the blood plasma of said subject.

15. (Original) A stable pharmaceutical formulation comprising apomorphine and one or more delivery-enhancing agents, wherein said formulation following mucosal administration to a mammalian subject yields a peak concentration of said apomorphine in a central nervous system tissue or fluid of said subject that is 10% or greater compared to a peak concentration of said apomorphine in a blood plasma of said subject.

16. (Original) A stable pharmaceutical formulation comprising one or more dopamine receptor agonist(s) and one or more delivery-enhancing agent(s), wherein said formulation following mucosal administration to a mammalian subject yields a peak concentration of said dopamine receptor agonist in a central nervous system tissue or fluid of said subject that is greater than a peak concentration of said dopamine receptor agonist in the central nervous system tissue or fluid of said subject following administration to said subject of the same concentration or dose of said dopamine receptor agonist to said subject by injection.

17. (Original) The formulation of claim 16, wherein the dopamine receptor agonist is apomorphine or a pharmaceutically acceptable salt or derivative thereof.

18. (Original) The formulation of claim 16, wherein said delivery-enhancing agent(s) is/are selected from:

(a) an aggregation inhibitory agent;

(b) a charge modifying agent;

(c) a pH control agent;

(d) a degradative enzyme inhibitory agent;

(e) a mucolytic or mucus clearing agent;

(f) a ciliostatic agent;

(g) a membrane penetration-enhancing agent selected from (i) a surfactant, (ii) a bile salt, (ii) a phospholipid additive, mixed micelle, liposome, or carrier, (iii) an alcohol, (iv) an enamine, (v) an NO donor compound, (vi) a long-chain amphipathic molecule (vii) a small hydrophobic penetration enhancer; (viii) sodium or a salicylic acid derivative; (ix) a glycerol ester of acetoacetic acid (x) a clyclodextrin or beta-cyclodextrin derivative, (xi) a medium-chain fatty acid, (xii) a chelating agent, (xiii) an amino acid or salt thereof, (xiv) an N-acetylamino acid or salt thereof, (xv) an enzyme degradative to a selected membrane component, (ix) an inhibitor of fatty acid synthesis, or (x) an inhibitor of cholesterol synthesis; or (xi) any combination of the membrane penetration enhancing agents recited in (i)-(x);

(h) a modulatory agent of epithelial junction physiology;

(i) a vasodilator agent;

(j) a selective transport-enhancing agent; and

(k) a stabilizing delivery vehicle, carrier, support or complex-forming species with which the dopamine receptor agonist is effectively combined, associated, contained, encapsulated or bound resulting in stabilization of the dopamine receptor agonist for enhanced mucosal delivery, wherein the formulation of said dopamine receptor agonist with said one or more delivery-enhancing agents provides for increased bioavailability of the dopamine receptor agonist in a central nervous system tissue or fluid of said subject.

19. (Original) The formulation of claim 16, wherein said delivery-enhancing agent(s) is/are selected from the group consisting of citric acid, sodium citrate, propylene glycol, glycerin, L-ascorbic acid, sodium metabisulfite, edetate disodium, benzalkonium chloride, sodium hydroxide and mixtures thereof.

20. (Original) The formulation of claim 1 or 16, wherein said formulations are substantially particulate free.

21. (Withdrawn) A method for treating or preventing a disease or condition in a mammalian subject amenable to treatment by therapeutic administration of a dopamine receptor agonist, comprising mucosally administering to said subject a pharmaceutical formulation comprising a dopamine receptor agonist and one or more delivery-enhancing agent(s) resulting in delivery of a peak concentration of said dopamine receptor agonist in a central nervous system tissue or fluid of said subject that is 5% or greater compared to a peak concentration of said dopamine receptor agonist in a blood plasma of said subject.

22. (Withdrawn) The method of claim 21, wherein said disease or condition amenable to treatment by therapeutic administration of said dopamine receptor agonist is Parkinson's disease.

23. (Withdrawn) The method of claim 21, wherein said disease or condition amenable to treatment by therapeutic administration of said dopamine receptor agonist is male or female erectile dysfunction.

24. (Withdrawn) The method of claim 21, wherein said disease or condition amenable to treatment by therapeutic administration of said dopamine receptor agonist is sexual dysfunction.

25. (Withdrawn) The method of claim 21, wherein said disease or condition amenable to treatment by therapeutic administration of said dopamine receptor agonist is male or female erectile dysfunction marked by engorgement of a male or female erectile tissue erectile tissue and/or enhanced neural stimulation potential of said erectile tissue, diminished sexual desire, or a diminished ability to reach orgasm during sexual stimulation in a male or female mammalian subject.

26. (Withdrawn) The method of claim 21, wherein said mucosal administration involves delivery of said formulation to a nasal mucosal surface of said subject.

27. (Withdrawn) The method of claim 21, wherein the dopamine receptor agonist is apomorphine or a pharmaceutically acceptable salt or derivative thereof.

28. (Withdrawn) The method of claim 21, wherein said dopamine receptor agonist is administered to said subject in an effective dose of between about 0.25 and 2.0 mg.

29. (Withdrawn) The method of claim 21, wherein said delivery-enhancing agent(s) is/are selected from:

(a) an aggregation inhibitory agent;

(b) a charge modifying agent;

(c) a pH control agent;

(d) a degradative enzyme inhibitory agent;

(e) a mucolytic or mucus clearing agent;

(f) a ciliostatic agent;

(g) a membrane penetration-enhancing agent selected from (i) a surfactant, (ii) a bile salt, (ii) a phospholipid additive, mixed micelle, liposome, or carrier, (iii) an alcohol, (iv) an enamine, (v) an NO donor compound, (vi) a long-chain amphipathic molecule (vii) a small hydrophobic penetration enhancer; (viii) sodium or a salicylic acid derivative; (ix) a glycerol ester of acetoacetic acid (x) a clyclodextrin or beta-cyclodextrin derivative, (xi) a medium-chain fatty acid, (xii) a chelating agent, (xiii) an amino acid or salt thereof, (xiv) an N-acetylamino acid or salt thereof, (xv) an enzyme degradative to a selected membrane component, (ix) an inhibitor of fatty acid synthesis, or (x) an inhibitor

of cholesterol synthesis; or (xi) any combination of the membrane penetration enhancing agents recited in (i)-(x);

(h) a modulatory agent of epithelial junction physiology;

(i) a vasodilator agent;

(j) a selective transport-enhancing agent; and

(k) a stabilizing delivery vehicle, carrier, support or complex-forming species with which the dopamine receptor agonist is effectively combined, associated, contained, encapsulated or bound resulting in stabilization of the dopamine receptor agonist for enhanced mucosal delivery, wherein the formulation of said dopamine receptor agonist with said one or more delivery-enhancing agents provides for increased bioavailability of the dopamine receptor agonist in a central nervous system tissue or fluid of said subject.

30. (Withdrawn) The method of claim 21, wherein said delivery-enhancing agent(s) is/are selected from the group consisting of citric acid, sodium citrate, propylene glycol, glycerin, L-ascorbic acid, sodium metabisulfite, edetate disodium, benzalkonium chloride, sodium hydroxide and mixtures thereof.

31. (Withdrawn) The method of claim 21, wherein said formulation mucosally administered to said subject yields a peak dopamine receptor agonist concentration in a cerebral spinal fluid of said subject that is between about 5-10% of the peak dopamine receptor agonist concentration in the blood plasma of said subject.

32. (Withdrawn) The method of claim 21, wherein said formulation mucosally administered to said subject yields a peak dopamine receptor agonist concentration in a cerebral spinal fluid of said subject that is about 10% or greater compared to the peak dopamine receptor agonist concentration in the blood plasma of said subject.

33. (Withdrawn) The method of claim 21, wherein said formulation mucosally administered to said subject yields a peak dopamine receptor agonist concentration in a cerebral spinal fluid of said subject that is about 15% or greater

compared to the peak dopamine receptor agonist concentration in the blood plasma of said subject.

34. (Withdrawn) The method of claim 21, wherein said formulation mucosally administered to said subject yields a peak dopamine receptor agonist concentration in a cerebral spinal fluid of said subject that is about 20% or greater compared to the peak dopamine receptor agonist concentration in the blood plasma of said subject.

35. (Withdrawn) The method of claim 21, wherein said formulation mucosally administered to said subject yields a peak dopamine receptor agonist concentration in a cerebral spinal fluid of said subject that is about 25% or greater compared to the peak dopamine receptor agonist concentration in the blood plasma of said subject

36. (Withdrawn) The method of claim 21, wherein said formulation mucosally administered to said subject yields a peak dopamine receptor agonist concentration in a cerebral spinal fluid of said subject that is about 30% or greater compared to the peak dopamine receptor agonist concentration in the blood plasma of said subject.

37. (Withdrawn) The method of claim 21, wherein said formulation mucosally administered to said subject yields a peak dopamine receptor agonist concentration in a cerebral spinal fluid of said subject that is about 35% or greater compared to the peak dopamine receptor agonist concentration in the blood plasma of said subject.

38. (Withdrawn) The method of claim 21, wherein said formulation mucosally administered to said subject yields a peak dopamine receptor agonist concentration in a cerebral spinal fluid of said subject that is about 40% or greater compared to the peak dopamine receptor agonist concentration in the blood plasma of said subject.

39. (Withdrawn) The method of claim 21, which yields a peak concentration of said dopamine receptor agonist in a central nervous system tissue or fluid of said subject that is 10% or greater compared to a peak concentration of said apomorphine in a blood plasma of said subject.

40. (Withdrawn) The method of claim 21, which yields a peak concentration of said dopamine receptor agonist in a central nervous system tissue or fluid of said subject that is greater than a peak concentration of said dopamine receptor agonist in the central nervous system tissue or fluid of said subject following administration to the subject of the same concentration or dose of said dopamine receptor agonist by injection.

41. (Withdrawn) The method of claim 21, wherein the dopamine receptor agonist is apomorphine or a pharmaceutically acceptable salt or derivative thereof.

42. (Withdrawn) The method of claim 21, wherein said delivery-enhancing agent(s) is/are selected from:

(a) an aggregation inhibitory agent;

(b) a charge modifying agent;

(c) a pH control agent;

(d) a degradative enzyme inhibitory agent;

(e) a mucolytic or mucus clearing agent;

(f) a ciliostatic agent;

(g) a membrane penetration-enhancing agent selected from (i) a surfactant, (ii) a bile salt, (ii) a phospholipid additive, mixed micelle, liposome, or carrier, (iii) an alcohol, (iv) an enamine, (v) an NO donor compound, (vi) a long-chain amphipathic molecule (vii) a small hydrophobic penetration enhancer; (viii) sodium or a salicylic acid derivative; (ix) a glycerol ester of acetoacetic acid (x) a clyclodextrin or beta-cyclodextrin derivative, (xi) a medium-chain fatty acid, (xii) a chelating agent, (xiii) an amino acid or

salt thereof, (xiv) an N-acetylamino acid or salt thereof, (xv) an enzyme degradative to a selected membrane component, (ix) an inhibitor of fatty acid synthesis, or (x) an inhibitor of cholesterol synthesis; or (xi) any combination of the membrane penetration enhancing agents recited in (i)-(x);

(h) a modulatory agent of epithelial junction physiology;

(i) a vasodilator agent;

(j) a selective transport-enhancing agent; and

(k) a stabilizing delivery vehicle, carrier, support or complex-forming species with which the dopamine receptor agonist is effectively combined, associated, contained, encapsulated or bound resulting in stabilization of the dopamine receptor agonist for enhanced mucosal delivery, wherein the formulation of said dopamine receptor agonist with said one or more delivery-enhancing agents provides for increased bioavailability of the dopamine receptor agonist in a central nervous system tissue or fluid of said subject.

43. (Withdrawn) The method of claim 21, wherein said delivery-enhancing agent(s) is/are selected from the group consisting of citric acid, sodium citrate, propylene glycol, glycerin, L-ascorbic acid, sodium metabisulfite, edetate disodium, benzalkonium chloride, sodium hydroxide and mixtures thereof.

44. (Withdrawn) The formulation of claim 1, which is substantially particulate free.

45. (Withdrawn) A method for treating or preventing a disease or condition in a mammalian subject amenable to treatment by therapeutic administration of a dopamine receptor agonist, comprising coordinately, mucosally administering to said subject a dopamine receptor agonist and one or more delivery-enhancing agent(s) resulting in delivery of a peak concentration of said dopamine receptor agonist in a central nervous system tissue or fluid of said subject that is 5% or greater compared to a peak concentration of said dopamine receptor agonist in a blood plasma of said subject.

19. (Original) The formulation of claim 16, wherein said delivery-enhancing agent(s) is/are selected from the group consisting of citric acid, sodium citrate, propylene glycol, glycerin, L-ascorbic acid, sodium metabisulfite, edetate disodium, benzalkonium chloride, sodium hydroxide and mixtures thereof.

20. (Withdrawn) The formulation of claim 1 or 16, wherein said formulations are substantially particulate free.

21. (Withdrawn) A method for treating or preventing a disease or condition in a mammalian subject amenable to treatment by therapeutic administration of a dopamine receptor agonist, comprising mucosally administering to said subject a pharmaceutical formulation comprising a dopamine receptor agonist and one or more delivery-enhancing agent(s) resulting in delivery of a peak concentration of said dopamine receptor agonist in a central nervous system tissue or fluid of said subject that is 5% or greater compared to a peak concentration of said dopamine receptor agonist in a blood plasma of said subject.

22. (Withdrawn) The method of claim 21, wherein said disease or condition amenable to treatment by therapeutic administration of said dopamine receptor agonist is Parkinson's disease.

23. (Withdrawn) The method of claim 21, wherein said disease or condition amenable to treatment by therapeutic administration of said dopamine receptor agonist is male or female erectile dysfunction.

24. (Withdrawn) The method of claim 21, wherein said disease or condition amenable to treatment by therapeutic administration of said dopamine receptor agonist is sexual dysfunction.

25. (Withdrawn) The method of claim 21, wherein said disease or condition amenable to treatment by therapeutic administration of said dopamine receptor agonist is male or female erectile dysfunction marked by engorgement of a male or female erectile tissue erectile tissue and/or enhanced neural stimulation potential of said erectile tissue, diminished sexual desire, or a diminished ability to reach orgasm during sexual stimulation in a male or female mammalian subject.

(iv) an enamine, (v) an NO donor compound, (vi) a long-chain amphipathic molecule (vii) a small hydrophobic penetration enhancer; (viii) sodium or a salicylic acid derivative; (ix) a glycerol ester of acetoacetic acid (x) a clyclodextrin or beta-cyclodextrin derivative, (xi) a medium-chain fatty acid, (xii) a chelating agent, (xiii) an amino acid or salt thereof, (xiv) an N-acetylamino acid or salt thereof, (xv) an enzyme degradative to a selected membrane component, (ix) an inhibitor of fatty acid synthesis, or (x) an inhibitor of cholesterol synthesis; or (xi) any combination of the membrane penetration enhancing agents recited in (i)-(x);

(h) a modulatory agent of epithelial junction physiology;

(i) a vasodilator agent;

(j) a selective transport-enhancing agent; and

(k) a stabilizing delivery vehicle, carrier, support or complex-forming species with which the dopamine receptor agonist is effectively combined, associated, contained, encapsulated or bound resulting in stabilization of the active agent for enhanced intranasal delivery, wherein the formulation of said dopamine receptor agonist with said delivery-enhancing agent(s) provides for increased bioavailability of the dopamine receptor agonist in a central nervous system tissue or fluid of said subject.

51. (Original) The pharmaceutical formulation of claim 1, comprising a plurality of mucosal delivery-enhancing agents selected from:

(a) an aggregation inhibitory agent;

(b) a charge modifying agent;

(c) a pH control agent;

(d) a degradative enzyme inhibitory agent;

(e) a mucolytic or mucus clearing agent;

(f) a ciliostatic agent;

(g) a membrane penetration-enhancing agent selected from (i) a surfactant, (ii) a bile salt, (ii) a phospholipid additive, mixed micelle, liposome, or carrier, (iii) an alcohol, (iv) an enamine, (v) an NO donor compound, (vi) a long-chain amphipathic molecule (vii) a small hydrophobic penetration enhancer; (viii) sodium or a salicylic acid derivative; (ix) a glycerol ester of acetoacetic acid (x) a clyclodextrin or beta-cyclodextrin derivative, (xi) a medium-chain fatty acid, (xii) a chelating agent, (xiii) an amino acid or salt thereof, (xiv) an N-acetylamino acid or salt thereof, (xv) an enzyme degradative to a selected membrane component, (ix) an inhibitor of fatty acid synthesis, or (x) an inhibitor of cholesterol synthesis; or (xi) any combination of the membrane penetration enhancing agents recited in (i)-(x);

(h) a modulatory agent of epithelial junction physiology;

(i) a vasodilator agent;

(j) a selective transport-enhancing agent; and

(k) a stabilizing delivery vehicle, carrier, support or complex-forming species with which the dopamine receptor agonist is effectively combined, associated, contained, encapsulated or bound resulting in stabilization of the dopamine receptor agonist for enhanced mucosal delivery, wherein said plurality of mucosal delivery-enhancing agents comprises any combination of two or more of said mucosal delivery-enhancing agents recited in (a)-(k), and wherein coordinate administration of said dopamine receptor agonist with said plurality of mucosal delivery-enhancing agents provides for increased bioavailability of the dopamine receptor agonist delivered to a mucosal mucosal surface of said subject.

52. (Original) The pharmaceutical formulation of claim 1, which incorporates a plurality of reducing agents to stabilize the dopamine receptor agonist.

53. (Original) The pharmaceutical formulation of claim 1, which incorporates a chitosan or chitosan derivative.

54. (Original) The pharmaceutical formulation of claim 1, wherein said chitosan or chitosan derivative is poly-GuD.

55. (Original) The pharmaceutical formulation of claim 1, which is pH adjusted to between about pH 3.0-6.0.

56. (Original) The pharmaceutical formulation of claim 1, which is pH adjusted to between about pH 3.0-5.0.

57. (Original) The pharmaceutical formulation of claim 1, which is pH adjusted to between about pH 3.0-4.0.

58. (Original) The pharmaceutical formulation of claim 1, which is pH adjusted to about pH 3.0-3.5.